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#1/Prizant

Applicant:
Serial No.:

Robert K. Jarvik
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For:

INTRAVENTRICULAR ARTIFICIAL HEARTS AND
METHODS OF THEIR SURGICAL IMPLANTATION AND
USE

Group Art Unit:

332

Examiner:

James Prizant

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Commissioner of Patents and Trademarks,
Washington, D.C. 20231, on March 14, 1990

John M. Kilcoyne, Reg. No. 33,100

Name of Applicant, Assignee or Registered

Representative

John M. Kilcoyne

Signature

March 14, 1990

Date of Signature

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This opportunity is taken to bring the references identified below to the
Examiner's attention.

U.S. Patent No. 4,453,537 - This patent relates to an apparatus for powering an
artificial heart. The apparatus comprises a reservoir implantable in the body and attachable to
a body muscle, a pacemaker having stimulatory electrodes for connection to the body muscle

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and sensor electrodes for sensing the physiological needs of the body and power output of the body muscle, and tubing for connecting the reservoir to the artificial heart.

U.S. Patent No. 4,152,786 - This patent relates to a compensator designed to be implanted within a living body and connected to a reciprocating blood pump with an external power source.

U.S. Patent No. 4,143,661 - This patent relates to an external power supply system used to operate an implanted electric-powered device such as a blood pump.

U.S. Patent No. 4,143,425 - This patent relates to an externally powered left atrial to descending thoracic aorta left ventricular assist device.

U.S. Patent No. 4,078,267 - This patent apparently relates to an artificial heart which is actuated by the motion of respiratory muscles. The operation of the heart is similar to that of a hydraulic diaphragm-piston pump.

U.S. Patent No. 4,051,840 - This patent apparently relates to a dynamic aortic patch which includes separable bladder and envelope components.

U.S. Patent No. 3,685,059 - This patent relates to a prosthetic device for implantation in or use with a living body. A substrate is coated with impermeable pyrolytic carbon which provides an inert and antithrombogenic outer surface.

U.S. Patent No. 3,668,708 - This patent relates to an artificial heart. The major structure of the heart comprises a number of resiliently flexible flat structural members disposed around a central support. The central support houses a pump, working fluid, control equipment and fluid flow ports. Physiological sensors, through appropriate circuitry, drive the pump that regulates the pumping rate of the artificial heart.

U.S. Patent No. 3,656,873 - This patent relates to a pneumatically driven by-pass pump system adapted for use in assisting or temporarily replacing the circulatory function of the heart.

U.S. Patent No. 3,641,591 - This patent relates to a blood pumping device to replace or temporarily assist the natural heart comprising a blood pumping chamber and an inflatable blood displacement member.

U.S. Patent No. 3,550,162 - This patent relates to a blood pump control system. The system comprises a variable volume pump for delivering hydraulic fluid to the pumping chamber of a heart assist pump, with the use of energy supplied from a power supply in the form of hydraulic fluid under pressure.

U.S. Patent No. 3,526,005 - This patent relates to a substrate for prosthetic devices. The substrate is coated with impervious isotropic pyrolytic carbon which provides an inert and antithrombogenic outer surface.

U.S. Patent No. 3,518,702 - This patent relates to an artificial heart system which is adapted to be powered and regulated by the body's chest and breathing muscles. The components of the artificial heart system comprise a reciprocating pneumatic or fluid pump, an artificial heart and a control means. The reciprocating pump is adapted to be operably connected to the body chest and breathing muscles to produce pneumatic or fluid pressure in response to the reciprocatory action of the body breathing.

U.S. Patent No. 3,513,486 - This patent apparently relates to a blood circulation pump having one or more pouches with a rotary shaft, driven by a rotating magnetic field transmission system outside the body.

U.S. Patent No. 3,491,377 - This patent relates to a heart assist apparatus capable of bypassing blood around a surgically installed clamp across the ascending aorta. Electromechanical means including a variable inductance element in the shell provides an analog signal in proportion to the instantaneous volume of the bladder. The analog signal is delivered to a hybrid logic circuit, and the output of the hybrid logic circuit is in turn delivered to an electropneumatic converter for causing a gas pressure to be supplied in proportion to the circuit output voltage.

U.S. Patent No. 3,478,695 - This reference relates to a pulsatile, passive filling, pump device.

U.S. Patent No. 3,182,335 - This patent apparently relates to dual-chamber artificial heart adapted to oscillate pneumatically.

Ross, et al. "The Architecture of the Heart in Systole and Diastole: Technique of Rapid Fixation and Analysis of Left Ventricular Geometry", Circulation Research, Vol. XXI, Oct., 1967, pp. 409-421 - This reference apparently relates to techniques for rapid fixation of the left ventricle in systole or diastole that have permitted analysis of ventricular geometry under known hemodynamic conditions.

Dodge, et al. "Usefulness and Limitations of Radiographic Methods for Determining Left Ventricular Volume", The American Journal of Cardiology, Vol. 18, July 1966, pp. 10-24 - This reference apparently relates to a description of the methods which have been most widely used for calculating left ventricular chamber volumes from biplane films, limitations of these methods and some applications of these methods in the study of patients with heart disease.

H. Arvidsson, "Angiocardiographic Determination of Left Ventricular Volume", Acta Radiologica, Vol. 56, Nov. 1961, pp. 321-339 - This reference apparently relates to a description of a method for angiocardiographic determination of left ventricular stroke volume, usable for quantitative calculation of the degree of mitral or aortic insufficiency.

The following references were uncovered in a search of the literature, but are not deemed to be of particular relevance:

U.S. Patent No. 4,652,263 - This patent relates to a macroscopically smooth, microporous, flexible, elastic tubular prosthetic device made from a substantially non-elastic woven fabric tube used to replace natural parts.

U.S. Patent No. 4,573,997 - This patent relates to a right ventricular assist device which utilizes a smooth segmented polyurethane sac housed in a rigid plastic casing. The sac is

an oblate spheroid with a single inlet and outlet passageway. Two means are disclosed for attaching the sac to the main pulmonary artery. In one means, provision is made for the attachment of a vascular graft to the passageway. The graft is then anastomosed to the main pulmonary artery in an end to side fashion. Alternately, the smooth segmented polyurethane sac may be formed with an elongate neck which is subsequently reinforced with a dacron graft, and the combined structure is then anastomosed to the main pulmonary artery in an end to side fashion.

U.S. Patent No. 4,240,409 - This patent was cited by the Examiner in application Serial No. 090,995.

U.S. Patent No. 4,187,852 - This patent relates to a synthetic elastomeric insoluble crosslinked polypentapeptide. The polypentapeptide is capable of calcification and the calcifiable material can be treated to make it useful in artificial vascular wall formation.

U.S. Patent No. 4,173,796 - This patent was cited by the Examiner in application serial No. 156,896.

U.S. Patent No. 4,173,689 - This patent relates to a synthetic polymer material for various prosthetic devices including vascular grafts, having mechanical compliance properties simulating that of a body tissue.

U.S. Patent No. 4,166,466 - This patent relates to a repeating hemostatic clip applying instrument and multi-dip cartridges therefor.

U.S. Patent No. 4,135,494 - This patent relates to an over-pressure protection device utilized for limiting the fluid pressure applied to a vein which has been removed from the body and which is being tested prior to transplantation within the body. The device limits the fluid pressure applied to the vein and therefore prevents subsequent deterioration of the vein.

U.S. Patent No. 4,131,604 - This patent was cited by the Examiner in application Serial No. 090,995.

U.S. Patent No. 4,080,958 - This patent relates to an apparatus having an external power source which aids blood flow.

U.S. Patent No. 4,041,931 - This patent relates to split ring markers fabricated in whole or in part from a radiopaque material to be sutured to tissue at the site of an anastomosis to provide a visual indication of its location when examined fluoroscopically.

U.S. Patent No. 4,034,742 - This patent relates to a pump chamber connected to a blood vessel by a single conduit. However, the device operates pneumatically thereby requiring an external power source.

U.S. Patent No. 4,015,590 - This patent relates to a pneumatically driven balloon activated blood pump for connection either in parallel with or to one side of the heart for temporary mechanical support of an inadequately functioning heart.

U.S. Patent No. 4,014,318 - This patent relates to circulatory assist devices which are implantable at various locations in the body. The assist devices include an electrically operated plunger which momentarily occludes the blood vessel during pumping.

U.S. Patent No. 3,911,898 - This patent relates to a heart assist device including blood pumping means connectible between a ventricle of the natural heart and the associated vascular system of the body to produce a pulsatile blood flow. Pumping control means is connected with the heart and the pumping means for regulating the pumping means in counterpulsation with the heart.

U.S. Patent No. 3,733,616 - This patent relates to an artificial heart pump which utilizes a plurality of electromagnets to alternately repel and attract a corresponding plurality of permanent magnets mounted on two flexible membranes each of which forms one of the heart's two ventricle chambers.

U.S. Patent No. 3,562,352 - This patent relates to copolymers which are characterized by a high degree of blood compatibility and therefore are useful in providing blood contact surfaces for devices used for implantation into the body.

U.S. Patent No. 3,512,183 - This patent relates to artificial blood vessels made of a bioelectric polyurethane.

U.S. Patent No. 3,505,987 - This patent relates to a counterpulsation system for aiding coronary circulation wherein an expansible impeller means is located within the aorta of a patient.

U.S. Patent No. 3,425,064 - This patent relates to a transducer for measuring the cardiac output of an artificial heart.

Bregman, et al. "Left Ventricular and Unidirectional Intra-aortic Balloon Pumping", The Journal of Thoracic and Cardiovascular Surgery, Vol. 68, No. 5, Nov. 1974, pp. 677-686 - This article relates to a discussion of intra-aortic balloon pumping as supportive treatment for the management of refractory left ventricular failure.

Donald, et al. "Circulatory Support by a Left Ventricular Balloon Pump", Cardiovascular Surgery 1970, p. I-96 to I-100 - This reference relates to the ability of a left ventricular balloon pump to provide support of the circulation when myocardial function has been severely impaired.

Also enclosed is a form listing the above references. Copies of the references can be found in the parent application, Serial No. 156,896, filed February 17, 1988. If requested, applicant will supply additional copies.

Consideration and making of record of the aforementioned references, and return to the undersigned of an appropriately endorsed copy of the form listing the above references, are requested.

Respectfully submitted,

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